REMARKS

Claims 1-19 were pending. Claims 7 and 9 are withdrawn from consideration. Claims 2 and 10 - 18 are canceled. Claims 1 is currently amended. No new matter is added. Applicants respectfully request reconsideration of the rejections.

The claims as currently amended cover methods for removing or repositioning lower GI stents; the claims pertaining to systems for lower GI stent repositioning and removal have been canceled.

In the Office Action dated December 12, 2003, all pending claims were rejected under 35 U.S.C 103(a) as being unpatentable over Giantureo et al (US 5,035,706) in view of Dua et al (US 6,302,917) and further in view of Cox et al (US 5,290,294). The Office Action states that Giantureo discloses all of the claimed elements except for the location of the stent and the removal device. Dua teaches the use of stents in the GI tract and Cox discloses the use of an apparatus with hinged forceps employed to pull objects into a protective sheath.

Applicants respectfully submit that the methods of the invention are not taught or suggested by the cited combination of art. Giantureo *et al.* teach a stent with tightening drawstring, but fails to teach or suggest methods of using such a device in the gastrointestinal tract. Dua teaches the use of stents in the gastrointestinal tract but fails to teach their removal.

Although individual elements were known – a stent with tightening drawstring; the use of stents in the gastrointestinal tract, and apparati with hinged forceps, the specific use of the present system for removal of gastrointestinal stents was not obvious to one of skill in the art. Evidence of this lack of obviousness is provided by documentation of an unmet need. There has been an absence of treatment for malignant bowel obstruction, in spite of the severity of the accompanying medical issues.

While in hindsight one can easily theorize combining an element from one source coupled with an element from another source, and use this combination to reconstruct the claimed invention. But in practice, real human beings are dying from a condition that can be alleviated with the present invention. The methods of the claimed invention were not obvious to these persons of ordinary skill.

Malignant bowel obstruction (MBO)is a serious condition occurring in up to 15% of cancer patients who receive palliative care (Soetikno et al, 1999; Gastrointest. Endosc. Clin. of North Amer., 9(3):447-458). In patients with ovarian cancer, MBO is the most frequent cause of death

(Ripamonti et al, 2002; Int. J. Gynecol. Cancer, 12(2):135-43). While the severity of this condition requires medical intervention, the morbidity and mortality rates associated with surgical intervention are high and sometimes untenable for patients with short life expectancies. Supportive therapy, however, is equally inadequate as the symptoms of MBO are difficult to alleviate with medication (Bethge et al, 1998; Am. J. Gastroenterol. 93:643). In addition, there are a significant number of patients who are too debilitated to withstand invasive surgery to alleviate the obstruction, with nearly 40% of patients with gastric cancer ineligible for this treatment (Ripamnti, 1994; Curr. Opin. Oncol., 6(4):351-357).

To improve the treatment of MBO, several groups have begun using expandable stents to mechanically relieve the obstruction (Soetikno et al, 1999; Gastrointest. Endosc. Clin. Of North Amer., 9(3):447-458). The preliminary results using expandable stents have been promising, but there are significant problems that must be overcome. Most significant is that the stents as currently designed and used are not suitable for long-term use (i.e. > 1 year). With time, the stents can become clogged with debris, move from their initial position, or lead to hyperplastic growth of the surrounding tissue. Because the patients in which the stents have been used do not have long life expectancies, this drawback was not a top concern. However, there are many patients in need of this treatment whose life-expectancy is significantly longer, including those in which the bowel obstruction is not caused by malignancy.

Without a doubt, the usefulness of lower GI stents would be significantly enhanced if there were a method to efficiently and non-surgically reposition or remove them. Such a method would enhance the efficacy, safety, and functionality of lower GI stents thereby expanding the patient pool eligible for this treatment and meeting a significant unmet medical need. The present application discloses such a method, and will provide significant benefit to patients over current medical practice. As such, Applicants argue that the methods described in the presently amended claims constitute patentable matter.

The Office Action states that "Giantureo discloses all of the claimed elements except for the particulars pertaining to the location of the stent and the removal device". As stated in the Abstract, the trailing ends of the monofilament thread used in Giantureo for stent retraction "extend from the stent and outside the body passageway". Reducing stent diameter for retrieval is achieved by "threading a tube of the free ends of the thread until the tube is adjacent to the stent" and "pulling the free ends of the thread through the tube".

The thread described in the present claims is in the form of a closed loop and does not extend outside the body passageway. Therefore, retrieval of the stent cannot be achieved as

described in Giantureo because there are no "trailing ends" of the drawstring to thread through a tube. Instead, the present application discloses a method for stent retrieval that uses a stent removal device with a grasping element that grabs the drawstring on the stent, tightens it to reduce the diameter, and pulls it into a protective sheath. As described, the stent in Giantureo would not work in association with such a retrieval device because the drawstring is not a closed loop and would not become tight when pulled from a single point along its length; the drawstring would simply be pulled away from the stent. Furthermore, the stent of Giantureo would not be practical in the GI tract as having a drawstring that extended outside the body passageway would not be feasible. Therefore, while Applicants acknowledge the contributions to the art of the cited patent, the design of the stent in Giantureo does not directly lead one of skill in the art to the method of stent removal as described in the present claims.

The Office Action states that using stents in the GI tract is known to those skilled in the art and cites Dua, which describes a stent-containing device for use in the upper GI tract, as an example of this.

However, the present application makes clear the fact that the use of stents in the lumen of the GI tract is part of current medical practice and that this alone is not novel. As stated above, it is the intended purpose of the method described in the present claims to improve the safety and efficacy of use of lower GI stents so that the patient pool that can benefit from such devices is expanded.

The Office Action states that the grabbing device in Cox, when combined with the disclosed stent in Giantureo, teaches the method disclosed in the present application. As stated above, the design of the stent disclosed in Giantureo is not able to function in the method described in the present claims due to the "open" design of the drawstring used for reducing the diameter of the stent. As such, any grasping device, including the one disclosed in Cox, is ill-suited for such a purpose. Moreover, the device in Cox is designed for removal of foreign bodies from body cavities and not for grasping and tightening a monofilament thread on a stent. As such, the design of the foreign body retrieval tools to be used in conjunction with the device in Cox et al is not appropriate for such a purpose.

Applicants respectfully argue that the methods for stent retrieval and repositioning as disclosed in the present claims are novel and constitute an inventive step. While with the advantage of hindsight it is possible to find individual elements of the disclosed method in prior

references, this alone is not sufficient to consider the present application without merit.

Therefore, it is respectfully submitted that Giantureo in view of Dua and Cox does not make obvious the claims as presented and that this rejection should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-219.

Respectfully submitted,
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Date: June 23, 2004

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1: Gastrointest Endosc Clin N Am. 1999 Jul;9(3):447-58. Related Articles, Links

Expandable metal stents for gastric-outlet, duodenal, and small intestinal obstruction.

Soetikno RM, Carr-Locke DL.

Division of Gastroenterology, VA Palo Alto Health Care System, Stanford University School of Medicine, Palo Alto, California, USA.

The treatment of patients who have malignant gastric-outlet, duodenal and small intestinal obstructions is difficult. The morbidity and mortality of palliative surgery in these patients is significant. It is not uncommon for patients to be treated with supportive therapy only, which unfortunately, neither relieves the severe nausea and vomiting, nor allows adequate food intake. Over the past few years, a number of studies have reported the safety and efficacy of self-expanding metal stents used to palliate malignant upper gastrointestinal obstruction. In this article, the authors focus on the use of self-expanding metal stents to treat malignant gastric-outlet, duodenal, and small intestinal obstructions.

Publication Types:
- Review
- Review, Tutorial

PMID: 10388860 [PubMed - indexed for MEDLINE]

1: Am J Gastroenterol. 1998 Apr;93(4):643-5.

Comment in:

- Am J Gastroenterol. 1998 Nov;93(11):2311-2.

Metal stents for the palliation of inoperable upper gastrointestinal stenoses.

Bethge N, Breitkreutz C, Vakil N.

Krankenhaus Neukolln Berlin, Germany.

We sought to determine the efficacy of metal stents in the palliation of malignant upper gastrointestinal stenoses. Six patients with inoperable malignant obstruction of the upper gastrointestinal tract, intractable nausea and vomiting, and an inability to maintain an oral intake were studied. A metal stent was inserted under endoscopic control and deployed in the stenosis. Stents were successfully deployed in all patients, and there were no immediate complications. All patients were able to eat after the procedure and parenteral nutrition was discontinued in all. Mean survival was 23 +/- 8.6 days. We conclude that metal stents represent a promising approach to the management of selected patients with malignant upper gastrointestinal stenoses and that their use warrants further study.

PMID: 9576464 [PubMed - indexed for MEDLINE]

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1: Int J Gynecol Cancer. 2002 Mar-Apr;12(2):135-43.

Palliative management of malignant bowel obstruction.

Ripamonti C, Bruera E.

Department of Palliative Care and Rehabilitation, National Cancer Institute, Milan, Italy.

Bowel obstruction may be a mode of presentation of intra-abdominal and pelvic malignancy or a feature of recurrent disease following anticancer therapy. Malignant bowel obstruction is well-recognized in gynecologic patients with advanced cancer. Retrospective and autopsy studies found the frequency at approximately 5-51% of patients with gynecological malignancy(1-7). Malignant bowel obstruction (MBO) is particularly frequent in patients with ovarian cancer where it is the most frequent cause of death(7). Patients with stage III and IV ovarian cancer and those with high-grade lesions are at higher risk for MBO as compared to patients with lower stage or low-grade tumors(1,8). Ovarian carcinoma accounted for 50% of small bowel obstruction and 37% of large bowel obstruction treated in a large gynecological oncology service(8-11).

Publication Types:
- Review
- Review, Tutorial

PMID: 11975672 [PubMed - indexed for MEDLINE]

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1: Curr Opin Oncol. 1994 Jul;6(4):351-7.

Management of bowel obstruction in advanced cancer.

Ripamonti C.

Palliative Care Division, National Cancer Institute, Milano, Italy.

Bowel obstruction is a common and distressing outcome in patients with abdominal or pelvic cancer. Patients may develop bowel obstruction at any time in their clinical history, with a prevalence ranging from 5.5% to 42% in those with ovarian cancer and from 10% to 28.4% in those with colorectal cancer. The causes of the obstruction may be benign postoperative adhesions, a focal malignant or benign deposit, or relapse or diffuse carcinomatosis. The symptoms, which are almost always present, are intestinal colic, continuous abdominal pain, nausea, and vomiting. Although surgery should be the primary treatment for malignant obstruction, it is now recognized that some patients with advanced disease or in generally poor condition are unfit for surgery and require alternative management to relieve distressing symptoms. A number of treatment options are now available for the patient with advanced cancer who develops intestinal obstruction. In this review, the indications for surgery are examined, the use of nasogastric tube and percutaneous gastrostomy evaluated, and the pharmacologic approach described.

Publication Types:
- Review
- Review, Tutorial

PMID: 7528546 [PubMed - indexed for MEDLINE]

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